

Esteem® – The Hearing Implant™

U.S. Clinical Trial Report 2008/09

- The Esteem® is superior to hearing aids in improving Speech Reception Threshold.
- The Esteem® is superior to hearing aids in improving Word Recognition Scores.
- The *Esteem*® showed **statistically significant improvement over hearing aids** as measured by the **Abbreviated Profile of Hearing Aid Benefit Questionnaire (APHAB)**.
- The Esteem® was rated superior to hearing aids by a majority of subjects implanted.
- The Esteem® is safe and causes no change in cochlear function.



US Clinical Trial Report 2008/09

A recent regulated clinical study conducted in the United States with patients suffering from sensorineural hearing loss found the $Esteem^{\otimes}$ Hearing Implant^{**} to provide statistically superior hearing restoration in a majority of patients as compared to that experienced by patients with hearing aids.

The *Esteem®* technology is the only solution available in the world found to be clinically superior to hearing aids for the alleviation of sensorineural hearing loss.

The average improvement in Speech Reception Threshold (SRT) scores with the *Esteem®* compared to the pre-implant hearing aid was 10.6 dB.

i Speech Reception Threshold tests determine the faintest level at which a person can hear and correctly repeat two-syllable (spondaic) words. When the individual hears a word, he or she repeats the word (or points to pictures) as the audiologist's voice gets softer and softer. The faintest level, in decibels, at which 50% of the two-syllable words are correctly identified, is recorded as the Speech Reception Threshold (SRT). A separate SRT is determined for each ear.

Patient Word Recognition Scores (WRS) with the *Esteem*® were equal to or better than WRS with hearing aids in 93% of patients (Word Recognition Scores at 50 dB Hearing Level).

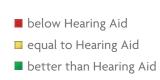
Word Recognition Tests attempt to evaluate how well a person can distinguish words at a comfortable loudness level. It relates to how clearly one can hear single-syllable (monosyllabic) words when speech is comfortably loud. In this test, the audiologist's voice (or a recording) stays at the same loudness level throughout. The individual being tested repeats words (or points to pictures). The percentage of words correctly repeated is recorded for each ear. Thus, a score of 100% would indicate that every word was repeated correctly. A score of 0% would suggest no understanding. Word recognition is typically measured in quiet.

60% of *Esteem*® patients had statistically significant improvement in their APHAB (Abbreviated Profile of Hearing Aid Benefit) scores compared to their hearing aid. *Esteem*® showed statistically significant mean benefit improvement over the subject's pre-implant hearing aid.

i The APHAB (Abbreviated Profile of Hearing Aid Benefit) is a 24-item self-assessment inventory in which patients report the amount of trouble they are having with communication or noises in various everyday situations. Benefit is calculated by comparing the patient's reported difficulty in the unaided condition with their amount of difficulty when using amplification. The APHAB produces scores for 4 categories: Ease of Communication (EC), Reverberation (RV), Background Noise (BN), and Aversiveness to Loud Sounds (AV).

WRS Improvement

The Esteem® Hearing Implant™ is superior in word recognition to the pre-implant hearing aids in 56% of subjects and is better than or equal to hearing aids in 93% of subjects according to the Thornton and Raffin model analysis.









4 months (4/54)

4 months (20/54)

4 months (30/54)

APHAB

Esteem® provides significantly more benefit than hearing aids at each of the four environmental subscales tested in the Abbreviated Profile of Hearing Aid Benefit Questionnaire (APHAB).

70% of the Esteem recipients found the Esteem® to be superior for (EC) Ease of Communication over their hearing aids. 61% of Esteem® recipients found Esteem® to be superior to hearing aids in (BN) Background Noise. 52% of the Esteem® recipients found Esteem® to be superior to their hearing aids in (RV) Reverberant situations. 61% of the Esteem® recipients found Esteem® to be superior to their hearing aids for (AV) Aversiveness to Loud Sounds.

In addition, the mean benefit improvement for the entire clinical subject population with Esteem® compared to the pre-implant hearing aid in each of the APHAB scales showed a statistically significant difference with Esteem® at the 4 month endpoint.

The APHAB benefit comparison between Esteem® and the baseline hearing aids clearly demonstrates that the Esteem® is statistically superior to hearing aids by significantly improving the mean benefit in all environmental categories and by providing significantly more benefit than hearing aids in over half (60%) of the subjects in this study.

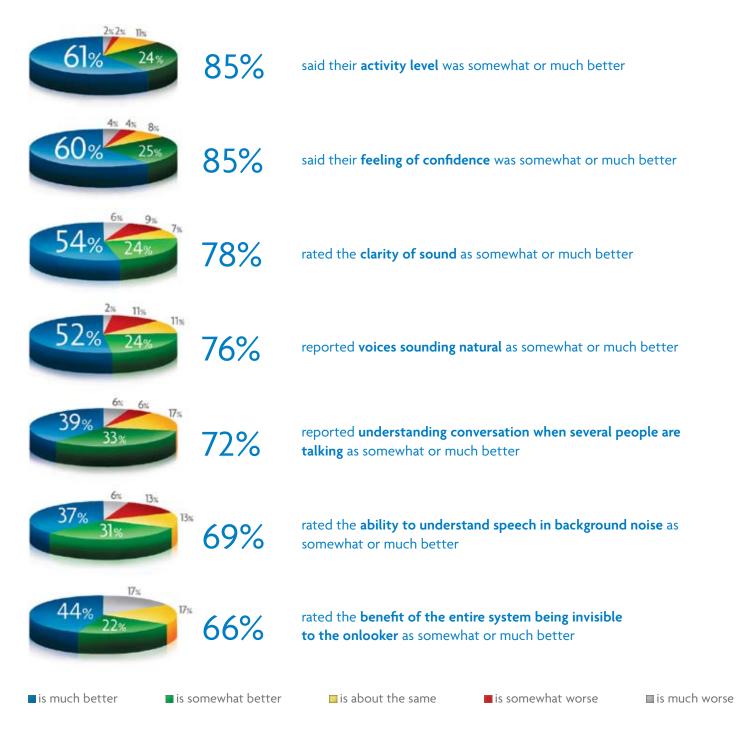
	4 Month APHAB Comparison Results N=53						
Individual Subjects	Total	EC	BN	RV	AV		
% Better HA > +22%	13/53 (25%)	15/53 (28%)	18/53 (34%)	14/53 (26%)	17/53 (32%)		
% Better HA +10 to 21%	14/53 (26%)	12/53 (23%)	10/53 (19%)	9/53 (17%)	11/53 (21%)		
% Better HA +5 to 9%	5/53 (9%)	10/53 (19%)	4/53 (8%)	5/53 (9%)	4/53 (8%)		
	32/53 (60%)	(37/53) 70%	32/53 (61%)	28/53 (52%)	32/53 (61%)		

Group Mean	Total	EC	BN	RV	AV
Mean Baseline Aided	18.7 ± 1.7	38.9 ± 2.9	29.8 ± 2.2	34.7 ± 2.6	-28.9 ± 2.9
Mean Esteem 4 month	28.3 ± 2.5	50.5 ± 3.1	39.5 ± 3.3	42.0 ± 3.5	-19.0 ± 3.8
Mean Improvement vs HA	10.9 ± 2.5	13.5 ± 3.2	10.2 ± 3.1	8.4 ± 3.1	11.4 ± 4.0

Quality of Life (QOL) Measurement

After four months of using the *Esteem*® Hearing Implant™, patients were asked to complete a questionnaire subjectively rating their experience with their *Esteem*® as compared to their experiences with their pre-implant hearing aid (aided condition).

The results of the questionnaire indicate that a strong majority of patients consider the *Esteem*® somewhat or much better than their hearing aid.



All implanted subjects in the Clinical Trial were current hearing aid users. The average time of hearing aid use was over 13 years. Of the subjects implanted, 86% used hearing aids in both ears.

